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BISNIS Search for Partners – Leads from the BioIndustry Initiative



INDUSTRY:
MEDICAL
EQUIPMENT AND
PRODUCTS,
PHARMACEUTICALS,
HEALTH CARE
SERVICES

COMPANY /
INSTITUTE:
Joint Stock Company BIOCAD
www.biocad.ru

COUNTRY: Russian
Federation

GENFERON®: A NOVEL THERAPEUTIC FOR UROGENITAL APPLICATIONS

ABSTRACT: In 2005, BIOCAD launched GENFERON®, an innovative product developed by Biocad's R&D unit, the Center of Immunological Engineering. GENFERON® is a suppository containing recombinant interferon- $\alpha 2b$, which is currently approved in Russia for use in patients with urogenital infections. GENFERON® is a unique drug containing Interferon with its profound antiviral and immunomodulatory activity. The drug stabilizes the cell membrane, stimulates tissue regeneration and rapidly relieves irritation and itching associated with urogenital infection. Local delivery helps to achieve a very high concentration of interferon- $\alpha 2b$ at the site of infection and at the same time eliminates risk of undesired systemic activity. Due to its immunomodulatory activity, GENFERON® is applicable in a broad variety of complex clinical situations, such as chronic infections with multiple chemoresistant pathogens. GENFERON® helps to overcome problems associated with chronic infection, such as, poor antigen presentation and suppression of immune reactions. Clinical trials of GENFERON® have confirmed high efficiency for the treatment of genital herpes, genital warts and chronic prostatitis. Incorporation of GENFERON® into the complex treatment regimens of patients with chronic prostatitis increases the rate of pathogen elimination and complete remission by more than 90%. Immunomodulatory and direct antiviral effects of GENFERON® make it a promising agent for therapy of chronic sexually transmitted diseases, including HPV infection – a leading cause of cervical cancer.

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OTHER INFORMATION

Institute representatives will be attending BIO2006 (Chicago, April 9 – 12, 2006) and welcome the opportunity to meet with interested parties during the event. For more information:

<http://www.biistate.net/docs/bio2006.php> or email:
EurasiaBio2006@biistate.net

TYPE OF PARTNERSHIP OFFERED: Licensing and partnering on clinical development and regulatory approval in major Western markets.

COMPANY / INSTITUTE ROLE: Partnership on clinical trials design, provision of preclinical and clinical data sets, licensing of formulation and manufacturing process / methods.

CURRENT STATE OF DEVELOPMENT: GENFERON® is approved in Russia for use in patients with urogenital infections; Phase II clinical trials are underway for the treatment of genital herpes, genital warts and chronic prostatitis.

INTELLECTUAL PROPERTY STATUS: The Genferon® suppository formulation is protected under patents of the Russian Federation ##2216345 & 2201212. PCT (Patent Convention Treaty) application is currently under preparation.

ABOUT COMPANY / INSTITUTE:

BIOCAD, a privately owned company established in 2001, is an emerging force in the pharmaceutical market in the Russian Federation. BIOCAD and its Chairman of the Board of Directors, Dmitry Morozov, have been prominently featured in recent publications, including *Nature Biotechnology* (Vol. 23, 2005) and *Wall Street Journal* (Apr 15, 2002). BIOCAD develops, manufactures and sells both generic and innovative biotechnology products. BIOCAD has established a state-of-the-art production facility in Moscow region and a top-notch research facility at the Center of Immunological Engineering (CIE), which develops novel therapeutics based on cytokines, antibodies and other recombinant proteins. In addition, BIOCAD has built an impressive marketing, sales and distribution network for pharmaceuticals in the Russian Federation. This distribution network was further expanded through strategic alliances with leading Russian distributors. In 2005 BIOCAD's share on the Russian market of immunobiological products increased from 2.8% to 3.3%. BIOCAD's manufacturing processes are compliant with domestic GMP standards, which are in turn harmonized with EU standards. Current capacity enables the production of 70 million suppositories per year. In 2006 the facility will be expanded to allow production of up to 10 million vials per year as well. BIOCAD is developing a new facility capable of large-scale production of recombinant proteins in mammalian cell cultures. **Center of Immunological Engineering, Ltd. (CIE)**, located in Lyubuchany (Moscow Region), a privately held subsidiary of BIOCAD, was established in 2001 on the basis of a former Soviet biotech research center. This research and development arm of BIOCAD focuses on creating new therapeutics

and commercializing existing technologies. CIE is fully equipped for processing of recombinant bacteria and viruses from an experimental set-up to a production scale. CIE spans the major part of biopharmaceutical development, from genetic engineering to preclinical study. CJSC BIOCAD, the parent company of the holding, manages clinical trials and the approval process. The distinguishing feature of BIOCAD is close collaboration between its highly qualified research and business teams.

PRODUCT	THERAPEUTIC AREA
BIOCAD: PRODUCTS ON THE MARKET	
Genferon	Urogenital infections
BIOCAD: PRODUCTS IN THE PIPELINE	
Recombinant G-CSF (Leucostim)	Hematology, oncology
Recombinant Interferon- α 2	Viral hepatitis, oncology
Recombinant Interferon- β	Multiple sclerosis, viral hepatitis
Recombinant L-Asparaginase	Hematology
Humanized monoclonal anti-CD20 antibody	Hematology
Recombinant IL-18	Oncology

MAJOR CUSTOMERS / INTERNATIONAL EXPERIENCE:

Customers include all leading Russian distributors of pharmaceutical products. BIOCAD has extensive experience with commercial contracts and international grants from organizations such as the International Science & Technology Center (www.istc.ru).

PARTNERSHIP OPPORTUNITIES FROM BII. The BioIndustry Initiative (BII) is a nonproliferation program of the US Department of State's Bureau of International Security and Nonproliferation - Office of Cooperative Threat Reduction (ISN-CTR). BII's mission is to counter the threat of bioterrorism through targeted transformation of former Soviet biological weapons research and production capacities.

DISCLAIMER. The leads are sourced by the BioIndustry Initiative through our partner organizations in Russia and other Eurasian countries. Leads are provided solely as an information resource and do not represent an endorsement by BII or the U.S. Departments of State and Commerce. Verification of the leads is the responsibility of the reader. Assistance conducting due diligence and negotiations with Eurasian companies/institutes may be provided in some cases. Contact BII for more details: bii@biistate.net.